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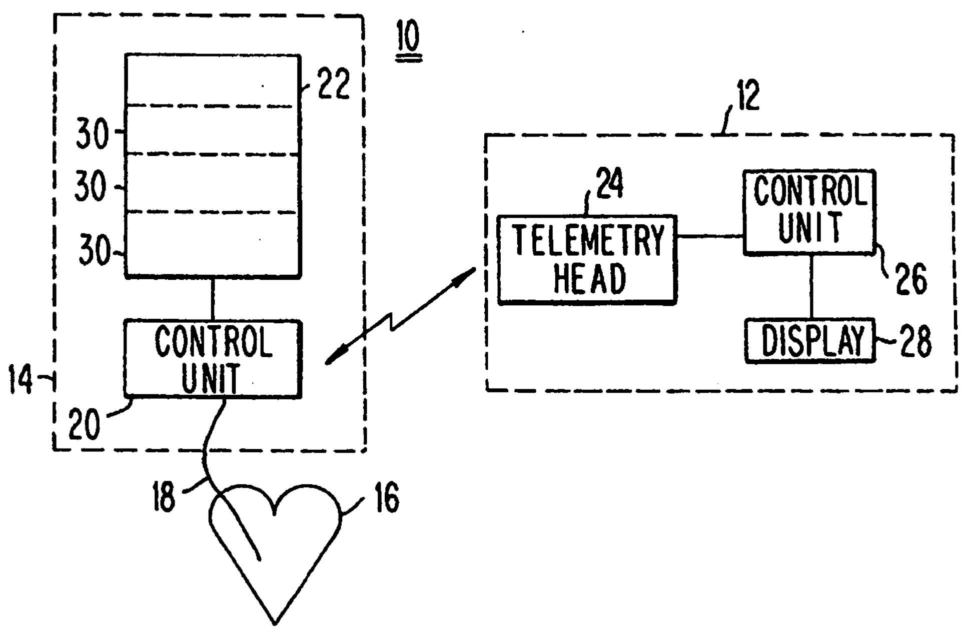
(54) Title: PROGRAMMING SYSTEM HAVING MULTIPLE PROGRAM MODULES

(57) Abstract

A programming system is provided in which a control program for an implantable medical device (14) is constructed from program modules (30) that are selected by a physician. Only the selected modules are loaded into the memory of the implantable medical device, each one of which provides the control functions necessary to provide a different therapy or diagnostic function. Because a physician typically does not need to elect all of the available therapies or diagnostic routines, the resulting control program may be smaller than a general purpose program designed to implement all of the possible treatments to a patient. Further a greater selection of therapies and diagnostic routines may be provided, without necessitating an increase in the memory capacity of the implantable medical device (14).



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PROGRAMMING SYSTEM HAVING MULTIPLE PROGRAM MODULES

Background of the Invention

This invention relates to implantable medical devices, and more particularly, to programming systems for providing implantable medical devices with control programs based on multiple program modules.

Implantable medical devices such as cardiac simulating devices, drug pumps, cochlear implants, and neurostimulators perform a variety of complex medical functions. For example, a cardiac stimulating device may detect various cardiac abnormalities and provide corresponding corrective therapies to a patient's heart. A cardiac stimulating device may also use diagnostic routines to monitor a patient's condition. Typically, cardiac stimulating devices such as pacemakers contain microprocessor-based control circuitry to implement the complex therapies and diagnostic routines that are used. Consequently, a control program is usually required to operate this type of device.

Cardiac stimulating devices generally contain a dedicated control circuit to provide the most basic, life-sustaining pacing functions. More complex functions are handled by executing the control program. For example, the control program is used to determine whether a cardioversion or defibrillation shock should be applied to a patient's heart. However, certain functions are of interest only to those patients who suffer from specific conditions. For example, if a patient suffers from tachycardia, a condition in which the heart beats too quickly, a diagnostic module that measures and stores data related to tachycardia can be used. However, this

function would most likely not be used by a patient who does not experience tachycardia episodes. Similarly, the ability of a control program to generate an antitachycardia therapy in response to a detected antitachycardia episode is only useful for patients who suffer occurrences of tachycardia.

Typically, however, cardiac stimulating devices are designed to operate under the control of a single control program. Although certain parameters may be adjusted, such as the base pacing rate, the control program itself is not altered by the physician. If a feature that the control program provides is not required, the physician disengages that function, so that it is not used. For example, U.S. Patent No. 4,958,632 (Duggan) shows a pacemaker with multiple functions that may be selected by a physician. However, the number of features that may be readily provided by the pacemaker in the Duggan patent is limited by the capacity of the memory within that device. Further, because the instructions used to provide each feature remain loaded in the memory of the device, even if a feature is not used, the memory reserved for that feature cannot be used to provide a different function. Although more memory could be provided, increasing the size of the memory is undesirable, because additional memory consumes more power and when a cardiac stimulating device's battery is exhausted the device must be surgically replaced.

Summary of the Invention

Therefore, in accordance with the present invention, a control program for an implantable medical device such as a cardiac stimulating device is provided that can be constructed by a physician or trained specialist from individual program modules, each providing the control necessary to implement a

single device function. Because a physician does not need to elect all of the available functions, the resulting control program is smaller than a general purpose program designed to implement all potentially useful device functions. Further, a greater selection of therapies and diagnostic routines may be provided, without necessitating an increase in the memory capacity of the device.

The modules can either be individually loaded into an implantable medical device such as a cardiac stimulating device, or can be combined and loaded as a single control program. If the modules are loaded separately, they can be placed in predetermined slots in memory or, alternatively, loaded at consecutive memory locations. Individual memory modules can be invoked when necessary by a root module or can be accessed by a function call from a root module. A root module may also be used to moderate communications between the separate modules. Further, modules may pass control from one to the next without using a root module. If a root module is provided in read-only memory (ROM), flags within the memory of the cardiac stimulating device may be set to indicate the memory locations of the program modules.

An apparatus is therefore provided which provides control of an implantable medical device that contains memory. The apparatus has circuitry for selecting, according to patient needs, a subset of program modules from a group of distinct program modules. The apparatus also has circuitry for loading the subset of program modules into the memory of the implantable medical device. The subset provides control of the operation of the implantable medical device for satisfying the patient needs.

A method for controlling the operation of an implantable medical device that contains memory into

which software can be loaded is also provided. The method involves selecting a subset of program modules from a group of distinct program modules according to patient needs. The method also involves loading the subset of program modules into the memory of the implantable medical device. The subset of program modules provides control of the operation of the implantable medical device for satisfying the patient needs.

A cardiac stimulating device is also provided that has memory into which software may be loaded. The cardiac stimulating device has circuitry for receiving a subset of cardiac program modules. The subset is selected from a group of distinct cardiac program modules according to patient needs. The cardiac stimulating device also has circuitry for storing the subset of cardiac program modules in the memory of the cardiac stimulating device. The subset of cardiac program modules provides control of the operation of the cardiac stimulating device for satisfying the patient needs.

A programming system is also provided that has an implantable medical device and a programmer. The implantable medical device, which may be implanted in the body of a patient, has first and second sensors for measuring first and second data signals. The implantable medical device also has memory for storing the first and second data signals. A control unit within the implantable medical device is used for allocating a portion of the memory to be used for storing the first data signals and a portion of the memory to be used for storing the second data signals. The programmer has an input interface for receiving commands to allocate the memory within the implantabl medical device. The programmer also has circuitry for generating allocation signals in response to the

commands and a telemetry head for transmitting the allocation signals to the implantable medical device. The control unit within the implantable medical device contains circuitry for receiving the allocation signals. The control unit allocates the memory to the first and second data signals in response to the allocation signals.

Brief Description of the Drawings

The above and other advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts throughout, and in which:

FIG. 1 is a schematic diagram of a programming system in accordance with the present invention, in which a subset of selected program modules is provided to an implantable medical device;

FIG. 2 is a schematic diagram of a procedure for selection of the desired program modules according to the present invention, in which the programmer creates a control program using the selected modules;

FIG. 3 is a schematic diagram of a procedure for program module selection according to the present invention, in which the modules are separately loaded into the memory of an implantable medical device;

FIG. 4 is a schematic diagram of the memory of an implantable medical device into which separate program modules have been loaded, such that a root module can invoke the desired modules as needed, in accordance with the present invention;

FIG. 5 is a schematic diagram of the memory of an implantable medical device into which separate program modules have been loaded, such that a root

module can moderate communications between modules, in accordance with the present invention;

FIG. 6 is a schematic diagram of the memory of an implantable medical device into which separate program modules have been loaded, such that a root module can make function calls to the program modules, in accordance with the present invention;

FIG. 7 is a schematic diagram of the memory of an implantable medical device into which separate program modules have been loaded, such that each module is allocated only as much memory as is required by that module, in accordance with the present invention;

FIG. 8 is a schematic diagram of the memory of an implantable medical device into which program modules have been loaded, such that after each module performs its function, it passes control to the next, in accordance with the present invention;

FIG. 9 is a schematic diagram of the memory of an implantable medical device into which program modules and data have been loaded, in accordance with the invention; and

FIG. 10 is a schematic diagram of the memory of an implantable medical device in which two sets of sensor data have been stored.

Detailed Description of the Preferred Embodiments

In accordance with the present invention, a programming system 10 is provided that is made up of both a programmer 12 and an implantable medical device, which could be, for example, a cardiac stimulating device 14, as shown in FIG. 1. The cardiac stimulating device 14 applies electrical stimulation to a patient's heart 16 using a lead 18. A control unit 20 preferably contains a microprocessor for executing program modules that have b en selected

by a physician to suit a patient's particular needs. Dedicated control circuitry contained within the control unit 20 can also be used to provide control of the cardiac stimulating device 14, in place of a microprocessor. The control unit 20 implements the instructions loaded in the memory 22. These instructions may be loaded into the cardiac stimulating device 14 by the programmer 12 via a telemetry head 24. The programmer 12 also contains a control unit 26 and a display 28.

The programming system uses multiple cardiac program modules 30 within the cardiac stimulating device 14. Because program modules vary in size, the programming system 10 preferably displays the memory requirements of each module on display 28 at step 32, as shown in FIG. 2 and at step 132, as shown in FIG. 3, which allows the physician to make an informed decision when balancing the benefits of different therapies and diagnostic routines. The amount of memory that is available in the cardiac stimulating device is also displayed. The memory requirements of the modules and the available memory in the cardiac stimulating device 14 can be displayed either numerically or graphically, using, for example, a pie chart. Alternatively, to simplify operation of the system, the memory requirements of the modules and the memory capacity of the cardiac stimulating devices can be hidden, so that this information is only available at the request of the user.

The physician selects program modules corresponding to those therapies and diagnostic routines that are thought to be the most effective for treating the patient at step 34, as shown in FIG. 2 and at step 134, as shown in FIG. 3. The actual selection may be made using any convenient user interface, such as a keyboard, lightpen or mouse. The

physician can select the desired modules from a menu that is displayed on the programmer's display 28. As the physician selects specific modules, the selections can be highlighted, and if a pie chart or other memory utilization display is used, the chart or display can be updated to reflect the amount of memory that remains available.

As shown in FIG. 2, the modules are combined by the programmer 12 (FIG. 1) to create the cardiac stimulating device control program at step 36. The control program for the cardiac stimulating device can be created by running linking software on the programmer. Alternatively, other equally suitable methods of providing an executable control program can be used. For example, the selected program modules could be merged together and subsequently compiled, rather than combining compiled object modules using a linker. Further, a custom routine can be used to combine the program modules into an executable program. Regardless of how the control program is created at step 36, the programmer 12 (FIG. 1) next loads the executable control program into the cardiac stimulating device at step 38. Either the entire program or specific portions of the program may be loaded. For example, it may be desired to clear the entire memory 22 (FIG. 1). In that case, all non-zero portions of the program could be loaded into the cleared memory 22. Alternatively, if only some of the program was modified, a smaller portion of the memory 22 might be cleared. Only the non-zero portions of the control program corresponding to the smaller portion of the memory 22 would then be loaded. Further, the memory need not be cleared before loading the program, because the existing data in the memory 22 may be directly replaced by the program data.

Referring to FIG. 1, loading may be initiated by using the programmer 12 to telemeter an appropriate loading command to the cardiac stimulating device 14. The control unit 20 contains telemetry circuitry for receiving and interpreting loading commands. If a command is received to begin loading the control program, further signals that are received by the cardiac stimulating device 14 are directed to the memory 22. For example, the loading command may contain a code which instructs circuitry within the control unit to write a specified quantity of incoming signals to a particular memory address. Alternatively, the control program can be loaded using a series of packets, each of which contains a target memory address, program data corresponding to a portion of the program to be loaded, and a command instructing the control unit 20 to store the program data at the target address. In any event, while the control program is being loaded, dedicated control circuitry contained within the cardiac stimulating device 14 performs basic pacing functions, although the control unit 20 does not execute the control program until the loading process is complete.

Another method of loading the control program into the memory 22 involves telemetering a reset command to the cardiac stimulating device 14, which causes the cardiac stimulating device to "reboot," by loading instructions from boot ROM in control unit 20 into memory 22. These instructions direct the cardiac stimulating device 14 to receive the control program code via telemetry. During loading of the control program, the control unit 20 does not execute the instructions in memory 22. However, dedicated control circuitry contained within control unit 20 continues to provide the patient with basic pacing functions. After the control program has

been loaded into memory 22, the cardiac stimulating device 14 provides the selected therapies to the patient as needed.

As shown in FIG. 3, after displaying the memory requirements at step 132, and after the physician has selected the desired therapies at step 134, the programmer may also load the selected program modules individually into the cardiac stimulating device at step 40, rather than loading an executable control program. FIGS. 4-6 are schematic diagrams of the memory of the cardiac stimulating device in which the program modules 35 have been loaded. The number of program modules that can be loaded into the device depends on the size of the modules and the amount of available device memory. In FIGS. 4-6, three program modules and a root module have been loaded. The root module contains instructions that allow the program modules to control the cardiac stimulating device during operation. For example, the root module may use a table in which various selected parameters are stored, such as the number and types of program modules that have been selected. The arrows in FIGS. 4-6 represent the general direction of the flow of control between modules.

One possible configuration of the root module and the program modules is shown in a memory 122 in FIG. 4. During operation, the root module 42 invokes the appropriate program modules according to a preprogrammed hierarchy. For example, a patient's physician might select both a diagnostic program module and antitachycardia program module. Initially, the root module 42 invokes the diagnostic module, so that the cardiac stimulating device 14 (FIG. 1) measures and stores the signals received from various sensors. During the diagnostic routine, the patient's cardiac condition is monitored, so that if the patient

experiences an episode of tachycardia, the root module 42 can invoke the antitachycardia module. When the tachycardia episode has been successfully terminated, the root module 42 invokes the diagnostic module again.

Another possible arrangement of program modules in a memory 222 is shown in FIG. 5. In contrast with the approach shown in FIG. 4, the root module 44 does not assume control of the cardiac stimulating device 14 (FIG. 10), but merely facilitates communication between respective modules. Control of the cardiac stimulating device 14 (FIG. 1) passes from one program module to the next as determined by the instructions within each of those modules.

An approach similar to the one shown in FIG. 4 is shown in FIG. 6. The memory 322 contains the root module 46, which retains primary control of the cardiac stimulating device 14 (FIG. 1). Unlike the arrangement shown FIG. 4, however, the root module 46 in FIG. 6 does not relinquish control to an invoked program module, but rather makes function calls to the appropriate modules as necessary. An alternative approach is for the root module to invoke modules according to a predetermined schedule.

The selection of which of the possible approaches to use is a design decision that is influenced by many factors, including the amount of memory that is available in the device, ease of programming, and the specific hardware features present in each device. Further, the selected subset of cardiac program modules does not need to be loaded into memory at evenly spaced address locations or slots, as shown in FIGS. 4-6. Rather, each module may be allocated only as much memory as is needed. For example, as shown in FIG. 7, module 1 requires more of

the memory 422 than module 2, so that module 1 uses more memory than module 2. Although this technique is not as simple as using fixed memory slots, it is more efficient, because the entire memory is used.

Modules can also be configured so that after each module performs its function it passes control to another module. For example, a first diagnostic module could be used to record the measured heart rate. After recording the rate, the first module could pass control to a second diagnostic module that monitors and records the signals measured by one of various other sensors. As shown in FIG. 8, upon completion of its function, module 1 passes control to module 2, which in turn passes control to module 3, and so forth. With this arrangement, a root module is not required.

If it is desired to store a root module in ROM, a set of registers or a portion of memory may be used to store a series of flags, which indicate where selected modules have been loaded into memory. For example, if memory 522 is divided into five segments, as shown in FIG. 9, the flags may be used to indicate whether a module is stored in a particular segment. Therefore, if modules were loaded into segments 48 and 50, the flags corresponding to those segments would be set to show that segments 48 and 50 contain executable instructions. If a module fills segment 52 completely and partially fills segment 54, then the flag corresponding to segment 52 would be set to show that segment 52 may be executed, whereas the flag corresponding to segment 54 would be set to indicate that segment 54 should not be executed, because it only contains a portion of a module. Similarly, if segment 56 contains data, the corresponding flag can be set to show that no executable instructions are present. The instructions for setting the flags ar

transmitted via telemetry when the modules are loaded into memory 522.

Regardless of what type of memory allocation scheme is used, after the modules have been loaded into the memory, error checking is preferably performed to ensure that the modules are loaded correctly. For example, even if the physician makes only minor changes in a previously prescribed set of therapies, the entire set of selected program modules or a portion of these modules can be retransmitted to the cardiac stimulating device 14 (FIG. 1). Alternatively, the device memory 22 (FIG. 1) can be tested to ensure each of the desired modules is present.

As described previously, an implantable medical device does not require a microprocessor. For example, a cardiac stimulating device 14 (FIG. 1) may use dedicated control circuitry to provide all of the necessary device functions. Cardiac stimulating devices such as these often contain a buffer for recording the time intervals between sensed cardiac events. In accordance with the present invention, it is also possible to store additional data, such as measurements made by motion sensors. Regardless of whether or not a microprocessor is used, if several sets of data are stored, a physician may often desire to focus on a particular set. For example, if a patient experiences discomfort that the physician believes is related to the response of the cardiac stimulating device to the magnitude of the signals measured by the motion sensor, the physician may wish to measure these signals more frequently and over a longer time period than would otherwise be the case. FIG. 10 shows a region of memory 622 that has been selectively configured by the physician into a larger segment 58, which is dedicated to storing data from

sensor 1 in detail, and a smaller segment 60 for storing the data from sensor 2. Memory 622 may therefore be allocated by the control unit (as in FIG. 1) in the same way that memory 422 (FIG. 7) is segmented based on the memory requirement of the various program modules.

Although the invention has been described primarily in the context of cardiac stimulating devices, it will be appreciated that the invention is not so limited. For example, the operation of implantable drug pumps, cochlear implants, and implantable neurostimulators can also be enhanced in accordance with the present invention.

Implantable drug pumps deliver drugs to patients on a predetermined schedule or when a sensor indicates that a patient needs a dose. Drug pumps such as these typically contain control circuitry and memory. Various drug delivery functions are provided by executing a control program. As with cardiac patients, each patient's individual condition differs. Depending on the specific drug that is delivered and the patient's lifestyle, drug pumps must provide different features. In accordance with the present invention, a control program is provided that is based on multiple program modules. Program modules can be selected by a physician to suit each individual patient. Because only a subset of the available modules is selected, the physician is able to choose from a wide range of drug therapy options without exceeding the memory capacity of the implantable drug pump.

Cochlear implants sense sound and provide corresponding electrical signals to stimulate a patient's nerves. A variety of signal processing techniques can be used to convert the sound signal into the stimulation signals. However, because

cochlear implants have limited memory, it has typically not been possible to implement all of the desired techniques. In accordance with the present invention, a cochlear implant control program is based on multiple program modules. The physician may therefore select from numerous signal processing routines, which would otherwise not be available. Further, the physician may test various modules to determine the best combination of signal processing techniques for an individual patient.

Implantable neurostimulators represent an additional class of implantable medical device that can be improved in accordance with the present invention by using multiple program modules. Implantable neurostimulators are often used to block pain by electrically stimulating nerves with a series of electrical pulses. Pulse width and amplitude vary widely. Further, it may be desirable to provide the pulses in a variable length burst. The various functions related to pulse generation can each be provided by a separate module. It is also possible to provide a program module to receive readings from various implanted sensors. As with the other types of implantable medical devices, neurostimulating devices have limited memory capacity. Therefore, the use of multiple program modules allows a physician to select from a wider range of options than if a single control program were used.

It will be understood that the foregoing is merely illustrative of the principles of this invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention.

CLAIMS

What is Claimed is:

1. An apparatus for providing control of an implantable medical device that contains memory, comprising:

means for selecting, according to patient needs, a subset of program modules from a plurality of distinct program modules;

means for loading the subset of program modules into the memory of the implantable medical device; and

wherein said implantable medical device comprises control means for controlling the operation of the implantable medical device in accordance with the program modules in the memory.

2. The apparatus defined in Claim 1, further comprising:

means for displaying the memory requirements of each of the program modules; and

means for displaying the memory capacity of the implantable medical device.

3. The apparatus defined in Claim 1, further comprising means for creating a control program from the subset of program modules.

4. The apparatus defined in Claim 3, wherein the means for loading comprises means for loading the control program into the memory of the implantable medical device.

5. The apparatus defined in Claim 3, wherein the means for creating the control program comprises a

linker for linking the subset of program modules to create the control program.

6. The apparatus defined in Claim 3, wherein the means for creating the control program comprises:

means for merging the program modules; and

means for compiling the merged modules to create the control program.

7. The apparatus defined in Claim 1, further comprising means for loading each of the modules in the subset of program modules into the memory of the implantable medical device separately.

8. The apparatus defined in Claim 7, further comprising means for loading a root program module into the memory of the implantable medical device.

9. The apparatus defined in Claim 7, wherein each of the program modules is loaded into a separate slot in the memory.

10. The apparatus defined in Claim 7, wherein the program modules are loaded into memory such that only as much memory as is required by each program module is used.

11. A method for controlling the operation of an implantable medical device that contains memory, into which program modules can be loaded, and a control unit that controls the operation of the implantable medical device in accordance with program modules in the memory, comprising the steps of:

selecting a subset of program modules, according to patient needs, from a set containing a plurality of distinct program modules; and

loading the subset of program modules into the memory of the implantable medical device.

12. The method defined in Claim 11, further comprising the step of displaying the memory requirements of each of the program modules.

13. The method defined in Claim 11, further comprising the step of displaying the memory capacity of the implantable medical device.

14. The method defined in Claim 11, further comprising the step of creating a control program from the subset of program modules.

15. The method defined in Claim 14, further comprising the step of loading the control program into the memory of the implantable medical device.

16. The method defined in Claim 14, wherein the step of creating the control program comprises the step of linking the subset of program modules to create the control program.

17. The method defined in Claim 14, wherein the step of creating the control program comprises the steps of:

merging the program modules; and

compiling the merged modules to create the control program.

18. The method defined in Claim 11, further comprising the step of loading each of the modules in the subset of program modules into the memory of the implantable medical device separately.

19. The method defined in Claim 18, wherein one of the program modules is a root program module.

20. The method defined in Claim 18, further comprising the step of loading each of the program modules into a separate slot in the memory.

21. The method defined in Claim 18, further comprising the step of loading the program modules into memory such that only as much memory as is required by each program module is used.

22. A cardiac stimulating device comprising:

memory into which cardiac program modules may be loaded;

means for receiving a subset of cardiac program modules, the subset being selected from a set containing a plurality of distinct cardiac program modules according to patient needs;

means for storing the subset of cardiac program modules in the memory; and

control means for controlling the operation of the cardiac stimulating device in accordance with the cardiac program modules stored in the memory.

23. The cardiac stimulating device defined in Claim 22, further comprising means for storing the cardiac program modules in the memory of the cardiac stimulating device as a control program.

24. The cardiac stimulating device defined in Claim 22, further comprising means for storing each of the modules in the subset of cardiac program modules in the memory of the cardiac stimulating device separately.

25. The cardiac stimulating device defined in Claim 22, further comprising means for storing a root cardiac program module.

26. The cardiac stimulating device defined in Claim 22, wherein each of the cardiac program modules is stored in a separate slot in the memory.

27. The cardiac stimulating device defined in Claim 22, wherein the cardiac program modules are loaded into memory such that only as much memory as is required by each cardiac program module is used.

28. A programming system comprising an implantable medical device that may be implanted in the body of a patient and a programmer, wherein:

the implantable medical device comprises:

first sensor means for measuring first data signals,

second sensor means for measuring second data signals,

memory for storing the first data signals and the second data signals, and

a control unit for allocating a portion of the memory to be used for storing the first data signals and a portion of the memory to be used for storing the second data signals; and

the programmer comprises:

an input interface for receiving commands to allocate the memory within the implantable medical device,

means for generating allocation signals in response to the commands, and

a telemetry head for transmitting the allocation signals to the implantable medical device, wherein the control unit contains circuitry for

receiving the allocation signals and the control unit allocates the memory for the first and second data signals in response to the allocation signals.

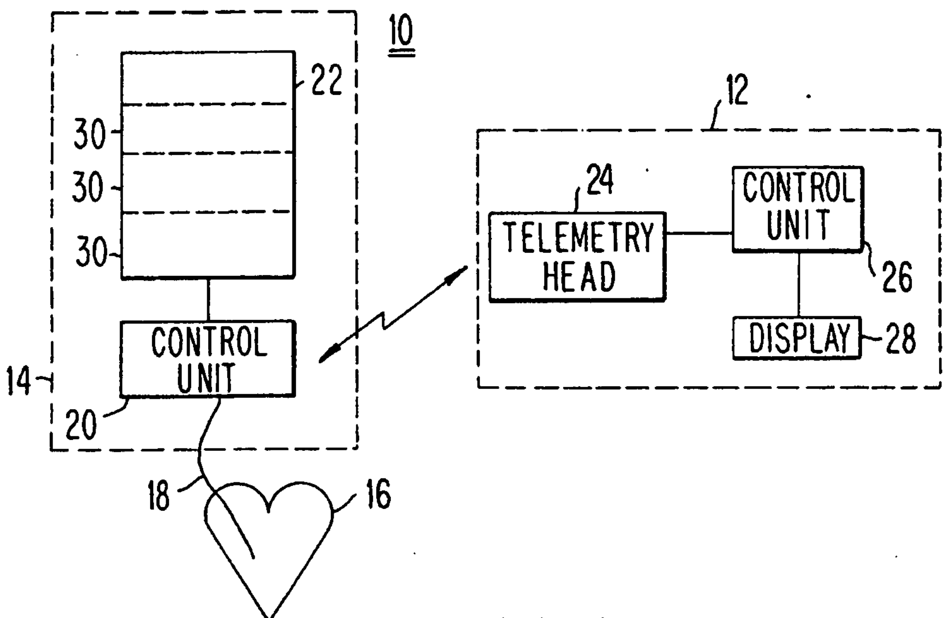
10
22
30
30
30
CONTROL UNIT
14
20
18
16
12
24
TELEMETRY HEAD
CONTROL UNIT
26
DISPLAY
28

FIG. 1

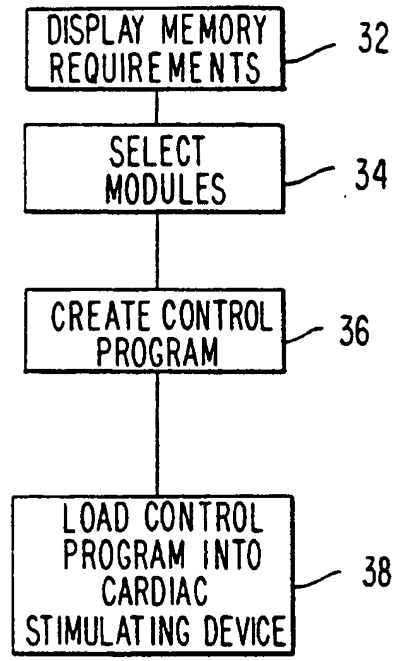
DISPLAY MEMORY REQUIREMENTS
32
SELECT MODULES
34
CREATE CONTROL PROGRAM
36
LOAD CONTROL PROGRAM INTO CARDIAC STIMULATING DEVICE
38

FIG. 2

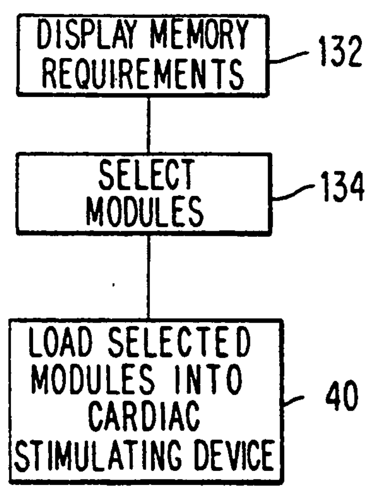
DISPLAY MEMORY REQUIREMENTS
132
SELECT MODULES
134
LOAD SELECTED MODULES INTO CARDIAC STIMULATING DEVICE
40

FIG. 3

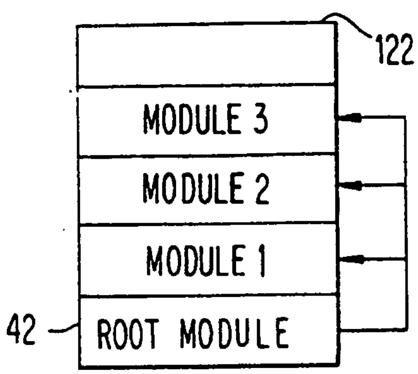

FIG. 4

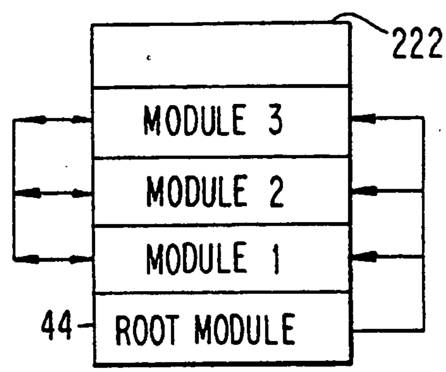

FIG. 5

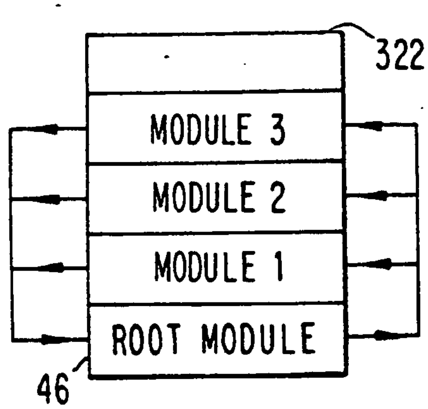

FIG. 6

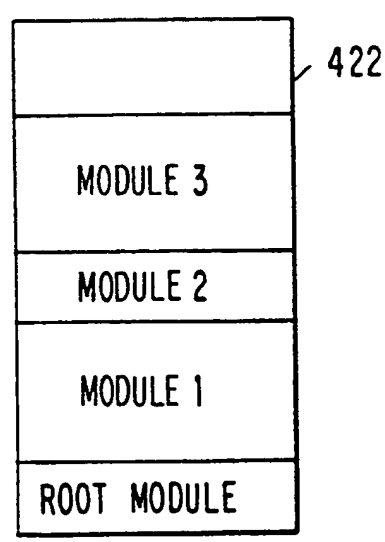

FIG. 7

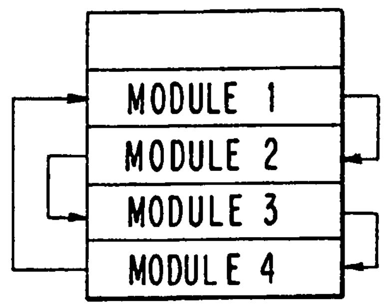

FIG. 8

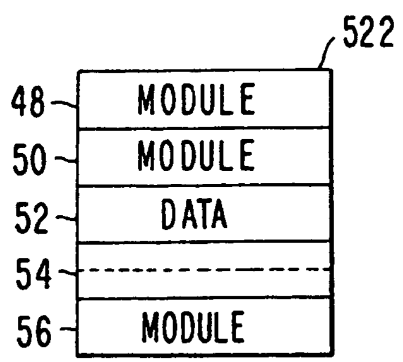

FIG. 9

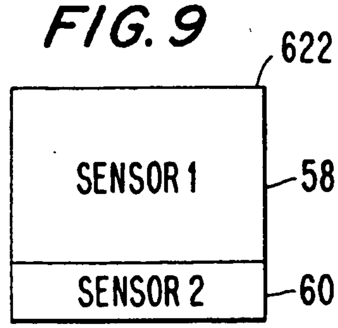

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/12990

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 1/37
US CL :607/30
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/30-32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,846,180, (BUFFET), 11 July 1989. See entire document.	1, 7-11, 18-27
X	US, A, 4,867,163, (SCHALDACH), 19 September 1989. See entire document.	28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 25 FEBRUARY 1995	Date of mailing of the international search report 24 MAR 1995
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